ORIGINAL

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA *ex rel.* KEVIN N. COLQUITT and KEVIN N. COLQUITT, Individually,	§	CIVIL ACTION NO.
	§	**FILED IN CAMERA AND UNDER SEAL**
	§	**PLAINTIFF'S COMPLAINT PURSUANT TO 31 U.S.C. §§ 3729-3732, FEDERAL FALSE CLAIMS ACT**
STATE OF ILLINOIS, *ex rel.* Kevin N. Colquitt; STATE OF CALIFORNIA, *ex rel.* Kevin N. Colquitt; STATE OF FLORIDA *ex rel.* Kevin N. Colquitt; STATE OF TEXAS *ex rel.* Kevin N. Colquitt; COMMONWEALTH OF MASSACHUSETTS *ex rel.* Kevin N. Colquitt; STATE OF TENNESSEE *ex rel.* Kevin N. Colquitt; STATE OF LOUISIANA *ex rel.* Kevin N. Colquitt; COMMONWEALTH OF VIRGINIA *ex rel.* Kevin N. Colquitt;	§	#4483 Receipt
	§	**JURY TRIAL DEMAND**
Plaintiffs,	§	3-06CV1769-M
vs.	§	
ABBOTT LABORATORIES F/K/A GUIDANT CORPORATION; CORDIS ENDOVASCULAR, A DIVISION OF CORDIS CORPORATION, a JOHNSON & JOHNSON PARTICIPATING COMPANY; and BOSTON SCIENTIFIC CORPORATION,	§	
Defendants.	§	

PLAINTIFF'S COMPLAINT PURSUANT TO 31 U.S.C. §§ 3729-3732, FEDERAL FALSE CLAIMS ACT

The United States of America, by and through *qui tam* Relator, Kevin N. Colquitt, brings this action under 31 U.S.C. §§ 3729-3732 (the "False Claims Act") to recover all damages, penalties and other remedies established by the False Claims Act on behalf of the United States and himself and would show the following:

PARTIES

1. Relator, Kevin N. Colquitt ("Colquitt"), is an individual citizen of the United States and a current resident of the State of Maryland. He is also attending Georgetown University Law Center in Washington, D.C. By virtue of his previous marketing positions with Guidant a/k/a Abbott he became aware of the pervasive off-label marketing schemes which have defrauded the federal and state governments as set forth herein.

2. Defendant Abbott Laboratories f/k/a/ Guidant Corporation (hereinafter "Guidant") is an Illinois corporation which has its principle place of business at 100 Abbott Park Road, Abbott Park, IL 60064-3500. Guidant has conducted the off-label, unlawful marketing of biliary stents for many years, all of which is set forth below. Guidant may be served by serving its agent for service of process, CT Corporation System at 350 North St. Paul, Dallas, TX 75201.

3. Defendant Cordis Endovascular, a Division of Cordis Corporation, a Johnson & Johnson Participating Company ("Cordis"), is a Florida Corporation which has its principle place of business at 14201 Northwest 60th Avenue, Miami Lakes, FL 33014. Cordis has conducted the off-label, unlawful marketing of biliary stents for many years, all of which is set forth below. Cordis may be served by serving its agent for service of

process, CT Corporation System, 1200 South Pine Island Road, Plantation, Florida 33324.

4. Defendant Boston Scientific Corporation ("BSC") is a Delaware Corporation which has its principle place of business at One Boston Scientific Place, Natick, MA 01760-1537. BSC has conducted the off-label, unlawful marketing of biliary stents for many years, all of which is set forth below. BSC may be served by serving its agent for service of process, Corporation Service Corporation at 701 Brazos Street, Suite 1050, Austin, TX 78701.

JURISDICTION AND VENUE

5. Jurisdiction and venue are proper in this Court for the following reasons:

a. Jurisdiction for this Court exists pursuant to the False Claims Act (31 U.S.C. § 3730(b)(1) and 31 U.S.C. § 3732(a)), because Relator's claims seek remedies on behalf of the United States for Defendants' multiple violations of 31 U.S.C. § 3729 some of which occurred in the Northern District of Texas, and because the Defendants transact substantial business within the Northern District of Texas.

b. Venue exists in the United States District Court for the Northern District of Texas pursuant to 31 U.S.C. § 3730(b)(1), because the Defendants are qualified to do business in the State of Texas and/or have transacted substantial business within the State of Texas and within the Northern District of Texas.

c. Venue exists in the United States District Court for the Northern District of Texas pursuant to 18 U.S.C. § 1965, because Defendants do business in the State of Texas and have conducted the unlawful, off-label marketing of biliary stents over a substantial period of time in the Northern District of Texas.

GENERAL BACKGROUND

Introduction

6. Relator began working in the medical device industry in January of 1997, at

which time he was employed as a Suture Support Representative by United States Surgical Corporation. Since that time, he served in the following additional positions: Account Representative-United States Surgical Corporation, Field Sales Representative/Field Sales Trainer-W. L. Gore & Associates, and Territory Manager-Guidant Corporation.

7. Relator was hired in February 2004 by Guidant Corp.'s Endovascular Solutions Division to be a Territory Manager in the Las Vegas, NV market. He worked in that position through April 2005, at which he made a lateral transfer to Washington, D.C. He remained employed as a Territory Manager in Washington, D.C. until June 2006, at which time he was laid off due to a buy-out of Guidant's stent business by Abbott Laboratories.

8. During his employment at Guidant, Relator primarily called on specific physician specialties: Interventional Cardiology, Interventional Radiology, and Vascular Surgery. Of the three specialties, only Interventional Radiologists were even qualified, by training and practice, to place stents in the biliary tree.

9. As part of his job, Relator was expected to educate physicians on the off-label (1) features and benefits; and (2) use of Guidant's devices. He was also expected to attend live cases with the physicians to offer technical support on the use of Guidant's products. During the two years Relator spent at Guidant and the hundreds of cases that he attended, Relator **never once** witnessed the use of any of the biliary stent devices being utilized, as approved by the FDA, for the biliary tree. Instead the biliary stents were routinely placed in the peripheral vascular system (Superficial Femoral Artery, Iliac Artery,

Popliteal Artery, Subclavian Artery). To market the biliary stents for non-approved usage, Relator and others were trained to robotically state the correct indication for use for the biliary products before discussing the non-approved uses with a customer. Nonetheless, Relator and other sales representatives made no genuine effort to promote the features and benefits or FDA approved use of the relevant products in the biliary tree, because **99% of the customers** had no biliary practice.

10. Before the September or October 2004 launch of the FDA approved carotid stent system, comprising about 10% of the market, the majority of Relator's sales came from the non-indicated [non-approved] use of Guidant biliary stents. The Relator's situation was not unique. Relator's fellow employees at Guidant were also required to sell, in the same off-label manner, the biliary stents for off-label indications, as was the competition at Cordis and BSC. The off-label marketing of the biliary stents was, and indeed still is, the industry standard in the peripheral interventional marketing arena.

11. The defendant companies, and others in the market, have all pursued a similar scheme in the off-label marketing of the biliary stents for off-label usage. First, they followed a relatively easy FDA pathway and received approval to market these stents for "biliary" use. Yet, they have almost entirely ignored this approved use in their marketing; instead, marketing the stents to the manifestly larger (99% of sales) "peripheral" market. The reason that the companies did not actively pursue a "peripheral" indication is that the FDA pathway to gain such an indication was, apparently, costly and time consuming, as well as less certain than the biliary pathway.

12. Today the off-label usage and marketing of "biliary" stents is rampant.

Companies that sell "biliary" stents derive about **99%** of the revenue for these products from **off-label marketing and usage**. They spend significant sums of money and time promoting the off-label usage through such activities as: (1) sponsoring training events for physicians to learn procedures where these devices would be used in a non-indicated, off-label fashion; (2) calling-on and entertaining almost exclusively physicians who are likely to use these devices in non-indicated procedures; and (3) developing business plans that are entirely dependant on the off-label usage of stents to achieve marketing objectives. Ironically, these companies virtually ignore the "biliary" market, the **only use** for which their products have FDA approval.

13. The Defendants have taken a gamble with the American public's health. They have chosen to off-label market these products for a non-indicated use for which they did not have strong scientific evidence regarding either efficacy or safety. Instead of seeking proof and governmental approval, they chose to circumvent the law in view of the extraordinary profitability. In the process, the defendants simply elevated financial returns above the needs of public policy which require following the law and promoting only approved products for the trusting public.

Two Regulatory Pathways for Medical Device Approval

14. Device manufactures ordinarily follow one of two regulatory pathways to seek FDA approval for medical devices: PMA and 510(k). A PMA submission requires that manufacturer submit scientific proof that the device is safe and effective for the intended use. This can be an expensive and time-consuming process for the manufacturer, as it usually entails conducting a clinical trial. The PMA pathway is usually reserved for new

and innovative devices and procedures. A 510(k) approval, on the other hand, requires only that the manufacturer demonstrate that the product is substantially similar to a reference product that already has FDA approval. A product that receives 510(k) clearance will receive approval for the same-labeled usage as the reference product.

Background on Off-Label Usage of Medical Devices

15. Off-label usage of a medical device is a use that has not been specifically approved by the FDA nor contraindicated. While manufacturers may not themselves *promote* such uses, it is not unlawful for doctors to employ or prescribe medical products for "unapproved" uses, long considered the "practice of medicine." Manufacturers are prohibited from promoting off-label usage. *Id.*

16. The FDA approves only those usages of a device that have been scientifically proven to be safe and effective. 21 U.S.C.A. § 360e. Because this burden of statistical proof is so high, it is impractical for manufacturers to study and prove every possible indication for every device. Physicians are permitted to use their judgment and discretion to use products in a non-indicated or off-label fashion in the practice of medicine. The violations herein do not implicate physicians. The relevant off-label violations are those of the manufacturers, alone.

A Brief History of Non-Coronary Stents

17. Stents are small tubular metal scaffoldings placed inside tubular structures (e.g., blood vessels, bile ducts, etc.) inside the body. Stents can be placed under x-ray guidance utilizing a minimally invasive approach. Usually the use of a stent will often enable a patient to avoid undergoing invasive surgery.

18. Malignant Biliary Strictures **(MBS)** can occur in patients that have cancer of the **pancreas, stomach, or liver**. A MBS prevents the normal drainage of bile into the digestive tract, leading to pain and discomfort. A patient diagnosed with MBS usually has a life expectancy of no more than 6 months to a year. The treatment of MBS is purely palliative, and it is designed to relieve the symptoms created by cancer, not to cure the disease.

19. Before the advent of interventional procedures, the only option to relieve a MBS was surgery. Performing surgery on an already frail cancer patient with a short life expectancy was not a desirable option for many reasons, so it was seldom performed, and patients, instead, had to suffer the painful symptoms of MBS.

20. Because MBS occurred in terminally ill patient population, and because there were no real viable options to treat MBS, stents were first studied for this application and eventually received PMA approval for the treatment of malignant biliary strictures.

21. Physicians, later, began using stent technology to treat diseases other than MBS. One of the greatest areas of interest was for the use of stents in the peripheral (non-coronary) arterial system. Because the potential market for peripheral arterial stents was geometrically greater than the market for MBS stents, the medical device industry responded enthusiastically. Manufacturers circumvented seeking PMA approval, which would have required the commitment of significant time and money, with the attendant uncertainties regarding safety and efficacy for the use of stents in the peripheral vasculature. Instead, the device manufacturers pretextually relied on the 510(k) process and utilized biliary stents as the reference product to unlawfully promote physicians to use

biliary stents in an off-label manner in order to tap into the prodigious peripheral vascular market potential for stents.

Current State of Affairs

22. Today at least **99%** of the stents used in the peripheral vascular system have, only, an indication for the treatment of MBS. These stents with an MBS indication are utilized at least 100's, not 1000's, of times more for the peripheral vasculature than the intended [approved] biliary tree. In fact many of the stents with a MBS indication are manufactured in configurations of diameter and length would make it impossible for them to be placed in any human biliary duct. Thus, while it is obvious that these stents have an indication, only, for the treatment of malignant biliary strictures, device manufacturers are producing the vast majority of them for use in the peripheral vascular system, notwithstanding the **lack of FDA approval for the use**.

23. Defendants and others in the biliary stent manufacturing and marketing proactively created the off-label market, because the indicated or approved use of the biliary stent was not financially rewarding. Defendants knew that health providers treating peripheral vascular disease constituted a significant target market, even though no FDA approval was in place or in process. No required studies were conducted by defendants to ensure that the biliary stents were either safe or effective for the non-indicated market that defendants created for peripheral vascular indications. The unlawful consortium of biliary manufacturers and marketers consciously flouted the law and created their own financial behemoth by providing significant financial incentives for health care providers. The healthcare providers were "guided" by the manufacturers to employ non-indicated biliary

stents in order to make more money! Because of the high correlation of coronary disease and peripheral vascular disease, the defendants' major focus was vascular surgeons and cardiologists, neither of which specialties involve the biliary organs. If they defendants are not required to obey the law and pay the damages resulting from their unlawful market promotion, the public policy underlying the False Claims Act will be undermined through "wink and nod" pretexts.

24. Device manufacturers use a marketing pretext by which they pretend that they are not marketing the biliary device for use in the peripheral vascular system. For example, all printed advertising material clearly states that these stents are only intended for the use of treating MBS. Similarly, sales reps are trained to preface any conversation with a physician about the use of stents in the peripheral vascular system with a "canned comment" that the stents are not indicated for "peripheral vascular system use." Any Guidant internal voicemail or e-mail communication about the use of stents in the peripheral vascular system was required to have a disclaimer that any such use was non-indicated. The manufacturers built a transparent façade that their biliary devices are only marketed in an on-label fashion, and that any communication about off-label uses is incidental, all of which is more pretext.

25. The pretext is exposed by the objective fact that vast majority of the biliary stents are being marketed and used in an off-label fashion. The manufacturers not only know it, but **bank heavily** on that fact. The MBS market is too small to support the industry, whereas the peripheral vascular market is large market forecasted to become much larger as the population ages. Other objective signs that manufacturers are off-label

marketing the usage include the fact that the majority of the customer contacts are vascular surgeons and interventional cardiologists who **never** perform any procedures on the bile duct and **never** treat MBS. The amount of revenue spent by the various marketing departments on advertising in journals and attending trade shows pertaining to peripheral vascular disease is **substantially greater** than the money spent on those pertaining to MBS. In fact, very little, if any, money was spent on marketing the product for MBS. Additionally, any review of the Guidant business plans objectively reveal that these stents are being primarily pushed off-label for the non-indicated usage target market.

CMS (Medicare/Medicaid) Consequences

26. CMS (Medicare/Medicaid) is the single largest reimburser for peripheral vascular procedures where stents are off-label marketed and used in a non-indicated manner. Manufacturers rely on CMS reimbursement information for peripheral vascular procedures to forecast the market for their biliary stents. Without CMS reimbursement to the hospitals and physicians for peripheral procedures utilizing biliary stents, the manufacturers' interest in marketing their biliary stents would be severely hampered. The indicated market for BMS procedures is **very small**, indeed.

27. 21 C.F.R. § 801.4 requires that manufacturers seek labeling for devices that is in accordance with their intended uses.[1] According to the regulation, the intended use

1 **§ 801.4 Meaning of "intended uses."** The words intended uses or words of similar import in §§ 801.5, 801.119, and 801.122 refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.

of a device should be determined by an objective standard. The totality of the circumstances has conclusively confirmed that the manufacturers' primary marketing activity has been off-label and oriented to the intended use of biliary stents for the treatment of peripheral arterial disease. While the manufacturers should have sought labeling for such use, they did not. While the proper manner of seeking such approval is through a PMA, I was unaware of any active effort to perform any PMA studies to enable a peripheral vascular approval for the biliary devices currently on the market. Manufacturers are required to follow the law in order to protect the public health.

Products in Question

28. The relevant products unlawfully marketed off-label by the defendants include, at least, the following:

Company	Product	Intended Use
Guidant	Herculink Plus .014	Palliation of malignant strictures in the biliary tree
Guidant	Omnilink .018	Palliation of malignant strictures in the biliary tree
Guidant	Omnilink .035	Palliation of malignant strictures in the biliary tree
Guidant	Dynalink .018	Palliation of malignant strictures in the biliary tree
Guidant	Dynalink .035	Palliation of malignant strictures in the biliary tree
Guidant	Absolute .035	Palliation of malignant strictures in the biliary tree
Cordis (J&J)	Smart Control	Palliation of malignant neoplasms in the biliary tree (pre-2006)
Cordis (J&J)	Palmaz Blue .014 RX	Palliation of malignant neoplasms in the biliary tree
Cordis (J&J)	Palmaz Blue .018 OTX	Palliation of malignant neoplasms in the biliary tree
Cordis (J&J)	Palmaz Genesis	Palliation of malignant neoplasms in the biliary tree
Cordis (J&J)	Palmaz	Palliation of malignant neoplasms in the biliary tree
Cordis (J&J)	Precise RX	Palliation of malignant neoplasms in the biliary tree
Cordis (J&J)	Precise	Palliation of malignant neoplasms in the biliary tree
Boston Scientific	Express Biliary SD Stent	Palliation of malignant neoplasms in the biliary tree
Boston Scientific	Express Biliary LD Stent	Palliation of malignant neoplasms in the biliary tree
Boston Scientific	NIR Biliary Stent	Palliation of malignant neoplasms in the biliary tree
Boston Scientific	Sentinol Biliary Stent	Palliation of malignant neoplasms in the biliary tree

Sample Violations

29. Though all of the above products are indicated for use in the biliary tree, the

manufacturers' actual target market is for use in the peripheral vascular system. As such, even a cursory analysis of the marketing practices of the above listed companies with regard to the listed products will reveal a virtually exclusive and continuous effort to unlawfully, off-label market these products for peripheral vascular use.

30. There are three (3) types of physicians who would use these biliary stents in an off-label fashion in the peripheral vascular system: (1) interventional cardiologists; (2) interventional radiologists; and (3) vascular surgeons. Of the three, only interventional radiologists are trained to place stents in the biliary tree. However, each of these companies focuses their marketing efforts on all three (3) specialties.

31. The Relator's first presentation during initial training at Guidant was delivered by Jim Neupert, Vice President Marketing. He spoke extensively about peripheral vascular and carotid disease. He estimated that peripheral vascular disease affects 5% of people over 50 years of age. He was very enthusiastic about the tremendous growth opportunity in the peripheral vascular market. There was scant, if any, mention of the malignant biliary stricture (MBS) market. Attached is a copy of his power point slides from that presentation.

32. Relator personally marketed, as trained and instructed, the Guidant stents in an off-label manner. He called on and asked interventional cardiologists and vascular surgeons to use the biliary stents in an off-label, non-indicated fashion. Relator attended and supported cases where Guidant stents were marketed off-label and used for peripheral vascular purposes. Relator's quota and compensation was predicated on the fact that he would market off-label the biliary stents for non-indicated uses. Every single one of Relator's peers were similarly trained in the off-label marketing of Guidant's biliary

stents.

33. On July 27, 2006 Relator specifically confirmed Cordis' off-label marketing of biliary stents over the years. Relator visited the Washington Hospital Center in Washington, D.C. He spoke with Mr. Holt Park of Cordis Endovascular (Johnson & Johnson) who was supporting a peripheral vascular intervention in which an interventional cardiologist was using a biliary stent in an off-label, non-indicated manner. Mr. Park confirmed that he had only seen the biliary stent used in the biliary tree a **couple of times in his career**, despite the fact that his territory produces over $ 4 million in annual revenue. Mr. Park also mentioned that Cordis Endovascular recently changed its compensation system away from rewarding the off-label sale of products in response to an employee lawsuit.

34. In 2005, Boston Scientific Corporation (BSC) sponsored a peripheral vascular interventional training course at Valley Hospital in Las Vegas, NV at which their products were marketed and demonstrated in an off-label manner. Dr. Carlos Fonte of Las Vegas, an interventional cardiologist, was the physician trainer for the event. The defendant's use of a third-party doctor was a superficial pretext for disclaiming any off-label marketing by the company, which financed the doctor's off-label marketing for the company during the training course. Form over substance was, and is, standard operating procedure.

35. The FDA offers a lawful process for the marketing of these devices. The manufacturers are not interested in compliance with the applicable laws. Unless forced to obey the law by the prosecution of this case, the violators will not modify their conduct. At the end of the day, this False Claims Act lawsuit will simply be an accounting suit, as

defendants' objective violations of the law just cannot be plausibly denied. Relator respectfully prays for all damages available under the False Claims Act of the federal government and the plaintiff states with similar statutes. Further, Relator respectfully requests that he be awarded attorneys' fees under the Common Fund doctrine from any settlement fund or recovery by judgment of benefits that this suit will generate for non-participatory states/beneficiaries.

Damages

36. Based upon marketing data provided by Guidant, the total peripheral and biliary market in 2003 in the U.S. was **$ 557 million**. In 2003, Cordis had 44% market share, Boston Scientific had 30%, and Guidant had 11%. Guidant projected that the peripheral/biliary market would grow at a 12% annual rate. Assuming that Guidant's projections were reasonably accurate, the total U.S. peripheral market in 2005 was just under **$ 700 million.** These estimates for the U.S. peripheral market include both the sale of stent and non-stent products. Relator would show that a conservative estimate, based upon his personal experience, of the ratio of stent sales to non-stent sales by Guidant, Cordis, and Boston in the peripheral/biliary market would be 2 to 1.

37. Assuming that the U.S. peripheral/biliary market remained a constant, no growth market after 2003, total peripheral sales by Guidant, Cordis, and Boston Scientific from the beginning of 2003 through the end of 2005 could be estimated at **$1.4 billion** ($557 million sales per year times 3 years times the 85% market share, cumulatively, for Cordis, Guidant, and Boston Scientific). Applying the 2:1 stent to non-stent sales ratio, Guidant, Cordis, and Boston Scientific sold over **$930 million** in stents to the

peripheral/biliary market in 2003, 2004, and 2005. Because stents placed in the biliary tree represent well less than 1% of the peripheral/biliary stent market, it is safe to assume that the above-mentioned companies sold off-label over **$ 900 million in stents for non-indicated usage in 2003, 2004, 2005**. Based upon a more severe, conservative assumption of similar sales of $200 million for each of the years of 2000, 2001 and 2002, the relevant cumulative sales for 2000-2002 would be **$600 million**. For the timeframe of 2000-2005 these defendants have conservatively marketed off-label **$1.50 billion** of their biliary stents for off-label, non-indicated usage over the past six (6) years. Medicaid, Medicare and the other federal or federal/state programs easily account for eighty percent **(80%)** of the market for the unlawfully marketed biliary stents; thus, the federal and state governments have been defrauded by these three defendants, alone, to the extent of **$1.2 billion**, cumulatively, in gross revenues over the last **six (6) years**. The other companies in the market are not joined, but they off-label market biliary stents in the same manner as the defendants.

38. These companies knowingly and purposefully chose not to pursue an indication for the intended target market for these biliary devices. In the process they have realized a significant amount of revenue by the off-label marketing of biliary stents for non-biliary usage. Relator requests a proper remedy for the defendants' **illegal sales** by disgorgement of the government's **$1.2 billion** payments for these off-label marketed products. Assuming, arguendo, that an alternative standard would be the disgorgement of the **gross profits, only,** realized by these companies' illegal activities, the gross profit margin on the sale of a stent would be, approximately, 75% of the revenues, according to

Guidant's management personnel. This margin is likely consistent for all three of the defendant manufacturers in this case. Thus, the total disgorgement of gross profits, an alternative remedy, should be **$900 million**. These figures represent only the actual losses to the federal and state governments, and they do not reflect any **multiple damages assessments** or **penalties** that are applicable. Defendants, since they are not self-reporting, should be required to pay at least double damages, if not treble damages.

FALSE CLAIMS ACT

39. This is an action which has alleged violations of the Federal False Claims Act, 31 U.S.C. §§ 3729-3732, seeking damages and civil penalties on behalf of the United States and Relator as a result of the Defendants' implied and express false statements and claims.

40. The False Claims Act provides that any person who knowingly submits or causes to be submitted to the United States for payment or approval a false or fraudulent claim is liable to the Government for a civil penalty of not less than $5500 and not more than $11,000 for each such claim, plus three (3) times the amount of damages sustained by the Government because of the false claim.

41. The False Claims Act allows any person having knowledge of a false or fraudulent claim against the Government to bring an action in Federal District Court for himself and for the United States Government and to share in any recovery as authorized by 31 U.S.C. § 3730. Relator claims entitlement to a portion of any recovery obtained by the United States as *qui tam* Relator/Plaintiff is, on information and belief, the first to file and, in any event an original source for the complaints in this action.

42. Based on these provisions, Relator on behalf of the United States Government seeks through this action to recover damages and civil penalties arising from the Defendants' submission of implied or express false claims for payment or approval. In this case, such off-label marketing of biliary stents resulted in government reimbursement for non-indicated uses. Claims by health care providers were submitted to Government entities for payment of fraudulently invoices reflecting such changes for non-indicated uses of biliary stents resulting from defendants' off-label marketing of the stents. *Qui tam* Relator/Plaintiff believes the United States has suffered significant damages, likely exceeding $1 billion (USD), as a result of the Defendants' false claims.

43. As required under the False Claims Act, *qui tam* Relator/Plaintiff has provided the offices of the Attorney General of the United States and the United States Attorney for the Northern District of Texas a statement of material evidence and information related to this complaint. That disclosure statement, supported by documentary evidence, supports the claims of wrongdoing.

CAUSES OF ACTION

A. Count I - False Claims (31 U.S.C. § 3729).

44. *Qui tam* Relator/Plaintiff realleges and hereby incorporates by reference each and every allegation contained in preceding paragraphs numbered 1 through 43 of this complaint.

45. Based on the acts described above, Defendants knowingly violated one or more of the following:

a. knowingly presented, or caused to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

b. knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

c. conspired to defraud the Government by getting a false or fraudulent claim allowed or paid;

d. knowingly made, used, or caused to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

46. The United States Government unaware of the falsity of these claims, records, and/or statements made by the Defendants and in reliance on the accuracy thereof, paid the Defendants for the fraudulent claims.

47. Because of the Defendants' fraudulent off-label marketing conduct, the United States and State Governments, respectively, "paid for," but did not receive indicated [FDA approved] products for the benefit of recipients of benefits under Medicare, Medicaid and other governmental programs. The federal and state governments, respectively, would not have paid reimbursement monies for the off-label marketed products had they known that the **unlawfully marketed products** were not qualified for reimbursement. The Defendants which unlawfully marketed the biliary stents violated the False Claims Act.

48. Due to the Defendants' knowing and unlawful conduct, the United States Government has suffered substantial monetary damages appearing to exceed $1 Billion.

RELIEF

49. On behalf of the United States Government, the Relator/Plaintiff seeks to recover monetary damages equal to three (3) times the damages suffered by the United

States Government. In addition, the Relator/Plaintiff seeks to recovery all available civil penalties on behalf of the United States Government in accordance with the False Claims Act.

50. The *qui tam* Relator/Plaintiff seeks, for his contribution to the government's investigation and recovery, to be awarded a fair and reasonable whistleblower award as provided by 31 U.S.C. § 3730(b) of the False Claims Act; additionally, he is entitled, in equity, to recover attorneys fees under the well-settled Common Fund doctrine from beneficiaries not contributing material time and expense to any successful settlement or recovery fund created as a result of Relator's filing and prosecution of this cause of action.

51. The *qui tam* Relator/Plaintiff seeks to be awarded all costs and expenses for this action, including statutory attorneys' fees and court costs from the Defendants.

52. Pre-judgment interest at the highest rate allowed by law and post-judgment interest as applicable.

PRAYER

WHEREFORE, Relator/Plaintiff prays that this District Court enter judgment on behalf of the Plaintiffs and against the Defendants, respectively, for the following:

a. Damages in the amount of three (3) times the actual damages suffered by the United States Government as a result of each Defendant's conduct;

b. Civil penalties against the Defendants, respectively, equal to $11,000 for each violation of 31 U.S.C. 3729;

c. *Qui tam* Relator/Plaintiff be awarded the a fair and reasonable sum to which the Relator is entitled under 31 U.S.C. § 3730(b); additionally, Relator is entitled, in equity, to recover attorneys fees from the fund created for non-participating beneficiaries (those not contributing material time and expense to generating any settlement or recovery from any Defendant) under the

Common Fund doctrine to be paid from the recovery fund generated for such non-participatory beneficiaries from the defendants;

d. *Qui tam* Relator/Plaintiff be awarded all costs and expenses of this litigation, including statutory attorneys' fees and costs of court;

e. Pre-judgment and post-judgment, as appropriate, interest at the highest rate allowed by law;

f. All other relief on behalf of the Relator/Plaintiff or the United States Government to which they may be justly entitled, under law or in equity, and which the District Court deems just and proper.

C. COUNT II - ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

53. Relator repeats and realleges each allegation contained in paragraphs 1 through 52 above as if fully set forth herein.

54. This is a *qui tam* action brought by Relator Kevin N. Colquitt and the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq*.

55. 740 ILCS 175/3(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, to an officer or employee of the State of a member of the Guard a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
>
> (3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

56. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind

in return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

57. The Defendants violated 740 ILCS 175/3(a) and knowingly caused as many as a hundred thousand false claims to be made, used and presented to the State of Illinois by their violations of federal and state laws, including 305 ILCS 5/8A-3(b), as a result of their off-label marketing of biliary stents, as described herein.

58. The State of Illinois, by and through the Illinois Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

59. Compliance with applicable Medicare, Medicaid and various other federal and state laws was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Illinois in connection with Defendants' fraudulent and illegal practices. As a result of Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has been damaged to the extent of many millions of dollars, exclusive of interest.

60. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 740 ILCS 175/3(b) on behalf of himself and the State of Illinois. This Court is requested to accept pendant jurisdiction of this related state claim, as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relator Kevin N. Colquitt respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF ILLINOIS:

(1) Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendants' fraudulent and illegal practices;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Illinois;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR, KEVIN N. COLQUITT:

(1) A fair and reasonable amount allowed pursuant to 740 ILCS 175/4(d) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

D. COUNT III - CALIFORNIA FALSE CLAIMS ACT

61. Relator repeats and realleges each allegation contained in paragraphs 1 through 60 above as if fully set forth herein.

62. This is a *qui tam* action brought by Kevin N. Colquitt and the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 *et seq.*

63. Cal. Gov't Code § 12651(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof, a false claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
>
> (3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.
>
> (4) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

64. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code § 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code §14107.2.

65. Defendants violated Cal. Gov't Code § 12651(a) and knowingly caused as many as a hundred thousand false claims to be made, used and presented to the State of California by their violations of federal and state laws, including, Cal. Bus. & Prof. Code § 650-650.1 and Cal. Welf, & Inst. Code §14107.2, by unlawfully off-label marketing biliary stents.

66. The State of California, by and through the California Medicaid program and other state health care programs, was unaware of Defendants' fraudulent and illegal practices and paid the claims submitted by health care providers and third party payers in connection therewith.

67. Compliance with applicable Medicare, Medi-Cal and various other federal

and state laws was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of California in connection with Defendants' fraudulent and illegal practices.

68. Had the State of California known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

69. As a result of Defendants' violations of Cal. Gov't Code §12651(a), the State of California has been damaged to the extent of millions of dollars, exclusive of interest.

70. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of himself and the State of California.

71. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Relator Kevin N. Colquitt respectfully requests this Court to award the following damages to the following parties and against Defendants, respectively:

To the STATE OF CALIFORNIA:

(1) Three times the amount of actual damages which the State of California has sustained as a result of each Defendant's fraudulent and illegal practices;

(2) A civil penalty of up to $10,000 for each false claim which each Defendant presented or caused to be presented to the State of California;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR, KEVIN N. COLQUITT:

(1) A fair and reasonable amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of statutory attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

E. COUNT IV - FLORIDA FALSE CLAIMS ACT

72. Relator repeats and realleges each allegation contained in paragraphs 1 through 71 above as if fully set forth herein.

73. This is a *qui tam* action brought by Kevin N. Colquitt and the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*

74. Fla. Stat. § 68.082(2) provides liability for any person who-

(a) knowingly presents, or causes to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;

(c) conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

75. Defendants violated Fla. Stat. § 68.082(2) and knowingly caused as many as a hundred thousand false claims to be made, used and presented to the State of Florida

by their violations of federal and state laws through unlawfully off-label marketing biliary stents as described herein.

76. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

77. Compliance with applicable Medicare, Medicaid and various other federal and state laws was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with Defendants' fraudulent and illegal practices.

78. Had the State of Florida known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

79. As a result of Defendants' violations of Fla. Stat. § 68.082(2), the State of Florida has been damaged to the extent of millions of dollars, exclusive of interest.

80. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of himself and the State of Florida.

81. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Relator Kevin N. Colquitt respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF FLORIDA:

(1) Three times the amount of actual damages which the State of Florida has sustained as a result of Defendants' fraudulent and illegal practices;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Florida;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR, KEVIN N. COLQUITT:

(1) A fair and reasonable amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

F. COUNT V - TEXAS FALSE CLAIMS ACT

82. Relator repeats and realleges each allegation contained in paragraphs 1 through 81 above as if fully set forth herein.

83. This is a *qui tam* action brought by Kevin N. Colquitt and the State of Texas to recover double damages and civil penalties under V.T.C.A. Hum. Res. Code § 36.001 *et seq.*

84. V.T.C.A. Hum. Res. Code § 36.002 provides liability for any person who:

(1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:

(a) on an application for a contract, benefit, or payment under the Medicaid program; or
(b) that is intended to be used to determine its eligibility for a benefit or payment under the Medicaid program.

(2) knowingly or intentionally concealing or failing to disclose an event:

(a) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of:

(i) the person; or
(ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and

(b) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;

(3) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:

(a) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

(b) knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program.

85. Defendants violated V.T.C.A. Hum. Res. Code § 36.002 and knowingly caused as many as a hundred thousand false claims to be made, used and presented to the State of Texas by their violations of federal and state laws, as described herein.

86. The State of Texas, by and through the Texas Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

87. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with Defendants' fraudulent and illegal practices.

88. Had the State of Texas known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

89. As a result of Defendants' violations of V.T.C.A. Hum. Res. Code § 36.002, the State of Texas has been damaged to the extent of millions of dollars, exclusive of interest.

90. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to V.T.C.A. Hum. Res. Code § 36.101 on behalf of himself and the State of Texas.

91. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

WHEREFORE, Relator Kevin N. Colquitt respectfully requests this Court to award

the following damages to the following parties and against Defendants:

To the STATE OF TEXAS:

(1) Two times the amount of actual damages which the State of Texas has sustained as a result of each Defendant's fraudulent and illegal practices;

(2) A civil penalty as described in V.T.C.A. Hum. Res. Code § 36.025(a)(3) for each false claim which Defendants cause to be presented to the state of Texas;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR, KEVIN N. COLQUITT:

(1) A fair and reasonable amount allowed pursuant to V.T.C.A. Hum. Res. Code § 36.110, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

G. COUNT VI - MASSACHUSETTS CLAIMS ACT

92. Relator repeats and realleges each allegation contained in paragraphs 1 through 91 above as if fully set forth herein.

93. This is a *qui tam* action brought by Kevin N. Colquitt and the State of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. 12 § 5(A) *et seq.*

94. Mass. Gen. Laws Ann. 12 § 5B provides liability for any person who:

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a

> false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;
>
> (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
>
> (4) is a beneficiary of an inadvertent submission of a false claim to the common wealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.

95. In addition, Mass. Gen. Laws Ann.§ 118E §41 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid program.

96. Defendants violated Mass. Gen. Laws Ann. 12 § 5B and knowingly caused as many as a hundred thousand false claims to be made, used and presented to the Commonwealth of Massachusetts by their off-label marketing violations of federal and state laws, as described herein.

97. The Commonwealth of Massachusetts, by and through the Massachusetts Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

98. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an

express condition of payment of claims submitted to the Commonwealth of Massachusetts in connection with Defendants' fraudulent and illegal practices.

99. Had the Commonwealth of Massachusetts known that Defendants' were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

100. As a result of Defendants' violations of Mass. Gen. Laws Ann. 12 § 5B, the Commonwealth of Massachusetts has been damaged in an amount far in excess of millions of dollars exclusive of interest.

101. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Mass. Gen. Laws Ann. 12 § 5(c)(2) on behalf of himself and the Commonwealth of Massachusetts.

102. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Relator Kevin N. Colquitt respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the COMMONWEALTH OF MASSACHUSETTS:

(1) Three times the amount of actual damages which the Commonwealth of Massachusetts has sustained as a result of Defendants' fraudulent and illegal practices;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the Commonwealth

of Massachusetts;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR, KEVIN N. COLQUITT:

(1) A fair and reasonable amount allowed pursuant to Mass. Gen. Laws Ann.12, §5F and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

H. COUNT VII - TENNESSEE FALSE CLAIMS ACT

103. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 102 above as if fully set forth herein.

104. This is a *qui tam* action brought by Kevin N. Colquitt and the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.*

105. § 71-5-182(a)(1) provides liability for any person who:

> (A) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
>
> (B) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
>
> (C) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

106. Defendants violated Tenn. Code Ann. § 71-5-182(a)(1) and knowingly caused as many as a hundred thousand false claims to be made, used and presented to the State of Tennessee by their violations of federal and state laws, as described herein.

107. Defendants' violations of § 71-5-182 and various other federal and state laws caused false claims to be submitted for payment to the State of Tennessee.

108. The State of Tennessee, by and through the Tennessee Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

109. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with Defendants' fraudulent and illegal practices.

110. Had the State of Tennessee known that Defendants violated the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

111. As a result of Defendants' violations of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

112. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. §

71-5-183(a)(1) on behalf of himself and the State of Tennessee.

113. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

WHEREFORE, Relator Kevin N. Colquitt respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF TENNESSEE:

(1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendants' fraudulent and illegal practices;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Tennessee;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR, KEVIN N. COLQUITT:

(1) A fair and reasonable amount allowed pursuant to Tenn. Code Ann. § 71-5-183(c) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

I. COUNT VIII - LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

114. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 113 above as if fully set forth herein.

115. This is a *qui tam* action brought by Kevin N. Colquitt and the State of

Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 437.1 *et seq.*

116. La. Rev. Stat. Ann. § 438.3 provides-

> (A) No person shall knowingly present or cause to be presented a false or fraudulent claim;
>
> (B) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds;
>
> (C) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim;

117. In addition, La. Rev. Stat. Ann. § 438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes, rebates, etc., directly or indirectly, overtly or covertly, in cash or in kind, for furnishing health care goods or services paid for in whole or in part by the Louisiana medical assistance programs.

118. Defendants violated La. Rev. Stat. Ann. §438.3 and knowingly caused as many as a hundred thousand false claims to be made, used and presented to the State of Louisiana by their violations of federal and state laws, as described herein.

119. The State of Louisiana, by and through the Louisiana Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

120. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also

an express condition of payment of claims submitted to the State of Louisiana in connection with Defendants' fraudulent and illegal practices.

121. Had the State of Louisiana known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

122. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. Ann. §439.1(A) on behalf of himself and the State of Louisiana.

123. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

WHEREFORE, Relator Kevin N. Colquitt respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF LOUISIANA:

(1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendants' fraudulent and illegal practices;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Louisiana;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR, KEVIN N. COLQUITT:

(1) A fair and reasonable amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

J. COUNT IV – VIRGINIA FRAUD AGAINST TAXPAYER ACT

124. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 123 above as if fully set forth herein.

125. This is a *qui tam* action brought by Kevin N. Colquitt and the Commonwealth of Virginia to recover treble damages and civil penalties under the Virginia Fraud Against Taxpayer Act, Va. Code § 8.01-216.01 et seq.

126. Va. Code § 8.01-216.01 et seq. provides liability for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;

(3) conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;

(4) has possession, custody, or control of property or money used, or to be used, by the Commonwealth and, intending to defraud the Commonwealth or willfully to conceal the property, delivers or causes to be delivered, less property than the amount for which the person receives a certificate of receipt;

(5) authorizes to make or deliver a document certifying receipt

> of property used, or to be used, by the Commonwealth and, intending to defraud the Commonwealth, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> (6) knowingly buys or receives as a pledge of an obligation or debt, public property from an officer or employee of the Commonwealth who lawfully may not sell or pledge the property; or
>
> (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth.

127. Defendants violated Va. Code § 8.01-216.03 and knowingly caused as many as a hundred thousand false claims to be made, used and presented to the Commonwealth of Virginia by their violations of federal and state laws, as described herein.

128. The Commonwealth of Virginia, by and through the Commonwealth of Virginia Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

129. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Virginia in connection with Defendants' fraudulent and illegal practices.

130. Had the Commonwealth of Virginia known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

131. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Va. Code § 8.01-216.5 on behalf of himself and the Commonwealth of Virginia.

132. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

WHEREFORE, Relator Kevin N. Colquitt respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the COMMONWEALTH OF VIRGINIA:

(1) Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Defendants' fraudulent and illegal practices;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the Commonwealth of Virginia;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR, KEVIN N. COLQUITT:

(1) A fair and reasonable amount allowed pursuant to Va. Code § 8.01-216.7 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Request for Jury Trial

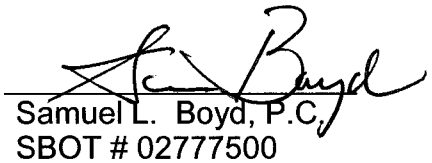
133. Relator respectfully requests a trial by jury as he is accorded under Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment of the U. S. Constitution.

Dated: September 26, 2006

UNITED STATES OF AMERICA, ex rel.
Kevin N. Colquitt

Respectfully submitted:

BOYD & ASSOCIATES



Samuel L. Boyd, P.C.
SBOT # 02777500
Catherine C. Jobe
SBOT # 10668280
6440 North Central Expressway
Suite 600
Dallas, Texas 75206-4101
Telephone (214) 696-2300
Facsimile (214) 363-6856

ATTORNEYS FOR RELATOR/PLAINTIFF

CERTIFICATE OF PREFILING DISCLOSURE TO THE GOVERNMENT OF THE UNITED STATES

This will certify that: (1) on the 5th day of September 2006 disclosure was provided via email to Russell Kinner, an attorney in the Civil Fraud Section of the Department of Justice in Washington, D.C.; (2) on the 26th day of September 2006, prior to the filing of this action, that disclosure was provided to the United States by email to kerry.willis@usdoj.gov of the Department of Justice, Civil Fraud Division, in Washington, D.C.; and (3) on the 25th day of September 2006 by telephone and on the 26th day of September 2006 by e-mail, Mr. Sean McKenna, AUSA, Northern District of Texas, was provided disclosure of the claims to be filed.

Samuel L. Boyd, P.C.

CERTIFICATE OF SERVICE

On this date, September 26, 2006, a copy of Relator's/Plaintiff's Complaint, Motion to Seal, Order to Seal and Disclosure Statement have been hand-delivered to offices of the Sean McKenna, Assistant United States Attorney for the Northern District of Texas, 1100 Commerce Street, 3rd Floor, Suite 300, Dallas, TX 75242 and via U.S. Mail, first class, transmitted to the U.S. Department of Justice, Attorneys, Civil Division, Post Office Box 261, Ben Franklin Station, Washington, DC 20044.

On this date, September 26, 2006, a copy of Relator's/Plaintiff's Complaint, Motion to Seal, Order to Seal and Disclosure Statement were formally served pursuant to FRCP 4(i)(1)(b), via Certified Mail, Return Receipt Requested, upon:

Alberto Gonzalez
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530-0001

Samuel L. Boyd P.C.